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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,144	02/06/2004	Durlin Hickok	17101-025001 / 24727-826	8562
7590 Stephanie Seidman Fish & Richardson P.C. 12390 El Camino Real San Diego, CA 92130-2081	04/06/2007		EXAMINER GRUN, JAMES LESLIE	
			ART UNIT 1641	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/06/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/774,144	HICKOK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 12 March 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3,4,6-11,13-15,17-23,25-38,40-46 and 48-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,3,4,6-11,13-15,17-23,25-38,40-46 and 48-64 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/12/07</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 March 2007 has been entered. Claims 2, 5, 12, 16, 24, 39, and 47 have been cancelled. Claims 1, 3, 4, 6-11, 13-15, 17-23, 25-38, 40-46, and 48-64 remain in the case.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6-11, 13-15, 17-23, 25-38, 40-46, and 48-64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 8 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 17 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

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In claim 26 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives “selected from...or” or “selected from the group consisting of...and” are acceptable.

In claim 35 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives “selected from...or” or “selected from the group consisting of...and” are acceptable.

Applicant's arguments filed 12 March 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above. Notwithstanding applicant's assertions to the contrary, limitations from the specification are not imported into the claims unnecessarily.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c ) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1, 3, 4, 6-11, 13, 17-19, 22, 23, 25, 26, 30, 31, 33-38, 40-44, and 48-64 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Leavitt et al. (WO 94/17405) in view of any of Johnson et al. (NEJM 293: 675, 1975), Meis et al. (Am. J. Obstet. Gynecol. 187: S54, 2002), or Keirse (Br. J. Obstet. Gynaecol. 97: 149, 1990), and further in view of Weiner et al. or Andersen et al. for reasons of record in the prior rejection of the similar subject matter of these claims.

Claims 1, 3, 4, 6-11, 13, 15, 17-23, 25-38, 40-44, and 48-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, and further in view of Weiner et al. or Andersen et al., and further in view of Dullien (US 5,480,776) for reasons of record in the prior rejection of the similar subject matter of these claims.

Claims 7, 14, 17-19, 22, 23, 25, 26, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, and further in view of Weiner et al. or Andersen et al., and further in view of Allen et al. (Exp. Biol. Med. 226: 498, 2001) or Olsen et al. (Lancet 339: 1003, 1992) for reasons of record in the prior rejection of the similar subject matter of these claims.

Claims 7, 14, 17-23, 25, 30-34, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leavitt et al., in view of any of Johnson et al., Meis et al., or Keirse, further in view of Weiner et al. or Andersen et al., further in view of Dullien, and further in view of Allen et al. (Exp. Biol. Med. 226: 498, 2001) or Olsen et al. (Lancet 339: 1003, 1992) for reasons of record in the prior rejection of the similar subject matter of these claims.

Applicant's arguments filed 12 March 2007 have been fully considered but they are not deemed to be persuasive.

Applicant's arguments regarding other methods of determining an indication of preterm delivery were not found relevant to the teachings of the Leavitt et al. reference applied in the rejections of record and were, thus, not found persuasive. Notwithstanding applicant's suggestions to the contrary, Leavitt et al. teach their determinations of biochemical markers of impending imminent preterm delivery and of fetal membrane status to aid clinical decisions regarding administration of treatments to prolong pregnancy in pregnant patients at 12 to 37 weeks gestation (see e.g. pages 4-6, 8). Applicant's suggestion, ten years later, to test the same markers for the same purpose as taught in the Leavitt et al. reference is not found unobvious for the reasons of record.

Notwithstanding applicant's assertions to the contrary, progestational agents are known as among the tocolytic agents that function to prevent or reduce contractions prior to preterm labor (see e.g. Andersen et al., da Fonseca et al.), and not different therefrom. One of ordinary skill in the art would, therefore, reasonably have known from the teachings of the art not to treat a patient already in established labor with a progestational agent. It is also noted that applicant's specification provides no working examples of pregnancy prolongation other than suggesting that which has been demonstrated in the art with progesterone (da Fonseca et al.) or 17 $\alpha$ -hydroxyprogesterone (Johnson et al., Yemini et al., Keirse, or Meis et al.) or omega-3 fatty acid supplementation (Allen et al. or Olsen et al.). Notwithstanding applicant's arguments to the contrary, applicant's specification provides no showing to support applicant's implication of unexpected results from, as set forth in the rejections of record, the combination of known

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markers of impending imminent preterm delivery and of fetal membrane status with known treatments for pregnancy prolongation.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Nothing in the combination of known markers of impending imminent preterm delivery and of fetal membrane status with known treatments for pregnancy prolongation is gleaned only from applicant's disclosure. Notwithstanding applicant's suggestion to the contrary, Leavitt et al. teach their determinations of biochemical markers of impending imminent preterm delivery and of fetal membrane status to aid clinical decisions regarding administration of treatments to prolong pregnancy in pregnant patients at 12 to 37 weeks gestation (see e.g. pages 4-6, 8). Applicant acknowledges that the treatments as instantly claimed, and as set forth in the art of record, are known to delay delivery and thereby prolong pregnancy (see e.g. pages 12-13 of the instant response).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). For example, applicant urges that Leavitt et al. do not teach determination of estriol. This is not found persuasive for the reasons

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of record because certain of the rejected claims do not require estriol determination because it is recited in the alternative. Moreover, for reasons of record, the inclusive list of biochemical markers of impending imminent preterm delivery in Leavitt et al. does not exclude estriol and its inclusion or substitution as such would have been obvious in view of Dullien. Applicant urges that Johnson et al., Meis et al., Keirse, or Allen et al. do not teach determinations of markers in their patients selected by other criteria as being at high risk for preterm delivery. This is not found persuasive for the reasons of record in view of the teachings in Leavitt et al. to test such patients in their method. Applicant urges that Leavitt et al. do not teach the specific use of progestational agents as the agents to prolong the pregnancy determined to be at risk for preterm delivery in the absence of ruptured membranes. This is not found persuasive for the reasons of record in view of the direct suggestion in the reference of Leavitt et al. to treat patients identified as such and in view of, firstly, the teachings of Johnson et al., Meis et al., Keirse, or Andersen et al., or, secondly, the teachings of Allen et al. or Olsen et al. Applicant urges that Dullien does not teach the specific use of progestational agents. This is not found persuasive for the reasons of record in view of the direct suggestion in the reference of Leavitt et al. to treat patients identified as at risk for preterm delivery in the absence of ruptured membranes and in view of, firstly, the teachings of Johnson et al., Meis et al., Keirse, or Andersen et al., or, secondly, the teachings of Allen et al. or Olsen et al.

Applicant's arguments drawn to a publication not of record, i.e. Ables et al. (2005), were not found persuasive.

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All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*JLGR*  
James L. Grun, Ph.D.  
March 28, 2007

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